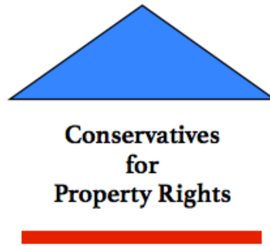

March 22, 2021

Technology Partnerships Office
National Institute of Standards and Technology
100 Bureau Drive MS 2201
Gaithersburg, MD 20899

RE: Notice of Proposed Rulemaking "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions," Docket No. 201207-0327

To whom it may concern:

Conservatives for Property Rights (CPR), a coalition of policy organizations representing thousands of Americans, writes in response to the National Institute of Standards and Technology's (NIST) request for comments regarding "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions," proposing revisions to regulations implementing the Bayh-Dole Act, Docket No. 201207-0327.

CPR has engaged in NIST's examination through the Return on Investment Initiative of federal policies, practices, and processes concerning the transfer of technology to private-sector and other partners. In our previous comments, CPR suggested Bayh-Dole needs few if any changes in either the law or regulation, and discussed how federal agencies could improve their level of performance in technology transfer and commercialization. We urged that Stevenson-Wydler Act reforms adopt the elements of Bayh-Dole that have made it so successful.

CPR said in 2018: "The key to successful technology transfer is transferring secure, enforceable private intellectual property (IP) rights. Streamlining processes, procedures, and rules across federal agencies for the transfer of technology to U.S. private-sector firms, especially of secure private IP rights, helps ensure the greatest bang for the taxpayer buck. Further, efficient, property rights-based tech transfer terms will maximize the contribution toward America's having a strong domestic industrial base that achieves competitiveness, provides jobs, and creates wealth due to our innovative edge." We believe this assessment remains true.

By this standard, CPR views NIST's proposed changes as generally remaining true to the Bayh-Dole framework. In general, the proposed revisions to the regulations promise Bayh-Dole's continued success. However, one proposal could upend Bayh-Dole's success and cause serious disruption.

The proposal for 401.6(e) says that march-in should not be based "exclusively" on a resulting product's "pricing." It should be noted that the law (35 U.S.C. § 203) specifies four narrow grounds for the government's exercising march-in rights. None of them mentions price. Thus, there is no statutory basis for injecting product price into march-in — much less for considering it "exclusively" or otherwise.

As Joseph Allen — the Senate staff aide who played a pivotal role for Sen. Birch Bayh in writing this law, helped implement the law in the Reagan administration, and directs the Bayh-Dole Coalition — has affirmed, price was intentionally unmentioned. Sens. Bayh and Robert Dole confirmed that this was an intentional omission from the statute on their part. "Bayh-Dole did not intend that the government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. *This omission was intentional* . . . ." (emphasis added)

Further evidence that Bayh-Dole march-in is not legally permissible nor available as a price control mechanism is the fact that both Democratic and Republican administrations have consistently declined to invoke it in connection with price. They have refused to legitimize numerous petitions over many years seeking march-in based on a product's price. Bipartisan officials have appropriately denied every such petition that advanced a false theory, properly finding no basis in the law.

With the absence of statutory language that would provide a basis for price consideration for march-in, to inject "pricing" into these decisions via regulation is unjustifiable and unfounded. The proposed regulatory rewrite would render the regulation inconsistent with the statute. To do so would risk the secure property rights on which entrepreneurs, institutions, investors, and others rely in deciding whether to attempt commercialization of a given invention.

Deciding to move forward with commercialization typically requires up-front investments of private dollars that far exceed, by orders of magnitude, the initial federal monies that led to a discovery that merely holds potential for practical benefit. There is no guarantee of commercial success. Thus, it is easily understood how the prospect of uncertainty caused by exposure to potential government takings of IP, long after federal funding way back at the point of invention has become essentially irrelevant, would lead many investors and entrepreneurs to pursue other, more certain enterprises.

With the pricing reference in 401.6(e) as proposed, it is highly likely to have a chilling effect on private firms that otherwise want to pursue commercialization of federally funded inventions. The National Institutes of Health (NIH) in 1989 started requiring a "reasonable pricing" provision in its Cooperative Research and Development Agreement (CRADA) federal contracting vehicle in order to obtain an exclusive license to NIH-funded technologies. The requirement sparked a significant drop in NIH CRADAs, from 42 in 1989 to an average of 32 the next six years. The uncertainty, diminished IP value, and weakened property rights rising from this CRADA clause led NIH to drop the provision. Then CRADAs with NIH immediately shot up to 87 agreements in 1996 and 153 in 1997. This should be a cautionary tale for NIST here.

Therefore, the proposal should drop any hint that price is relevant in connection with march-in, much less lawful. CPR would find the recommendation of several commenters, removal of the words "exclusively" and "of the contractor," acceptable to resolve our concern. Otherwise, the good achieved by other changes put forth in this rulemaking could be cancelled by this one.

Beyond this inadvisable NIST proposal, we remark on three specific proposals.

First, a welcome proposal (401.14(a)(2)) clarifies that the government's rights to use of a "subject invention" do not apply to a contractor's privately funded inventions.

Second, allowing agencies to waive taking title to a contractor's invention for noncompliance with certain requirements is positive. The proposal would revise 401.14(d)(2). Loss of title to intellectual property is significant and detrimental, especially for small businesses and for entrepreneurs attempting to build a business around a patented invention. Thus, the ability to cure noncompliance along the lines of form-and-manner violations is constructive.

Third, CPR applauds revisions formally recognizing confidential business information in contractors' submissions, at 401.13. This confidentiality duty would require agencies not to disclose confidential, privileged, proprietary information through the Freedom of Information Act (FOIA) or other means. This change should help assure contractors their sensitive business information is secure, as it should be. We suggest that providing more of a blanket protection of all "subject invention" information would bolster this important safeguard.

Aside from the unwelcome injection of product price in connection with march-in, other proposed revisions appear consistent with the spirit of Bayh-Dole.

* * *

In conclusion, Conservatives for Property Rights appreciates NIST's efforts to improve federal tech transfer. However, weakening Bayh-Dole's quiet title in private-sector commercializers' intellectual property would be an unfortunate turn.

CPR encourages NIST to proceed with these recommendations, after removing the pricing reference from 401.6(e), as in the best interest of the country and for promoting America's industrial competitiveness and innovative edge.

Respectfully,

James Edwards
Executive Director
Conservatives for Property Rights